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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94F-0334]

Morton International, Inc.; Filing of Food Additive Petition;  
Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Morton International, Inc., to indicate that the petitioner has proposed that the food additive regulations be amended to provide for the safe use of methyltin-2-mercaptoethylolate sulfide used alone or in combination with several other optional substances as a heat stabilizer for use in rigid poly(vinyl chloride) and rigid vinyl chloride copolymers intended for use in the manufacture of pipes and pipe fittings that will contact water in food processing plants.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER of October 21, 1994 (59 FR 53193), FDA announced that a food additive petition (FAP 4B4430) had been filed by Morton International, Inc., 2000 West St., Cincinnati, OH 45215. The petition proposed that the food additive regulations in § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) be amended to provide for the safe use of methyltin-2-mercaptoethyl oleate sulfide mixtures as heat stabilizers for use in polyvinyl chloride pipes intended for transporting water for food contact.

Subsequent to the publication of the filing notice, FDA has determined that methyltin-2-mercaptoethyl oleate sulfide is a complex mixture of one or more of the following:

1. 9-octadecenoic acid (Z)-, 2-mercaptoethyl ester, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 68442-12-6); or
2. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, 2-mercaptoethyl decanoate, 2-mercaptoethyl octanoate, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 151436-98-5); or
3. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 201687-57-2).

In addition, FDA has determined that the petition also proposes that the methyltin-2-mercaptoethyl oleate sulfide may be used in combination with the following optional substances:

1. 2-mercaptoethyl oleate (CAS Reg. No. 59118-78-4), or 2-mercaptoethyl tallate (CAS Reg. No. 68440-24-4), or 2-mercaptoethyl octanoate (CAS Reg. No. 57813-59-9), or 2-mercaptoethyl decanoate (CAS Reg. No. 68928-33-6), alone or in combination;

2. 2-mercaptoethanol (CAS Reg. No. 60-24-2);

3. Mineral oil (CAS Reg. No. 8012-95-1); or

4. Butylated hydroxytoluene (CAS Reg. No. 128-37-0).

Finally, FDA has determined that the petition requests the use of methyltin-2-mercaptoethyl oleate sulfide and the above optional substances as a heat stabilizer in rigid poly(vinyl chloride) and rigid vinyl chloride copolymers, complying with §§ 177.1950 and 177.1980, respectively. The rigid poly(vinyl chloride) and rigid vinyl chloride copolymers are intended for use in the manufacture of pipes and pipe fittings that will contact water in food processing plants.

Therefore, FDA is amending the filing notice of October 21, 1994, to indicate that the petitioner requests that the food additive regulations be amended to provide for the safe use of methyltin-2-mercaptoethyl oleate sulfide that is defined as one or more of the following:

1. 9-octadecenoic acid (Z)-, 2-mercaptoethyl ester, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 68442-12-6); or

2. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, 2-mercaptoethyl decanoate,

2-mercaptoethyl octanoate, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 151436-98-5); or

3. Fatty acids, tall oil, 2-mercaptoethyl esters, reaction products with dichlorodimethylstannane, sodium sulfide, and trichloromethylstannane (CAS Reg. No. 201687-57-2); as a heat stabilizer for use in rigid poly(vinyl chloride) and rigid vinyl chloride copolymers, complying with §§ 177.1950 and 177.1980, respectively, intended for use in the manufacture of pipes and pipe fittings that will contact water in food processing plants.

In addition, FDA is amending the filing notice of October 21, 1994, to indicate that the petitioner requests that the food additive regulations be amended to provide for the safe use of methyltin-2-mercaptoethyl oleate sulfide in combination with the following optional substances:

1. 2-mercaptoethyl oleate (CAS Reg. No. 59118-78-4), or 2-mercaptoethyl tallate (CAS Reg. No. 68440-24-4), or 2-mercaptoethyl octanoate (CAS Reg. No. 57813-59-9), or 2-mercaptoethyl decanoate (CAS Reg. No. 68928-33-6), alone or in combination;

2. 2-mercaptoethanol (CAS Reg. No. 60-24-2);

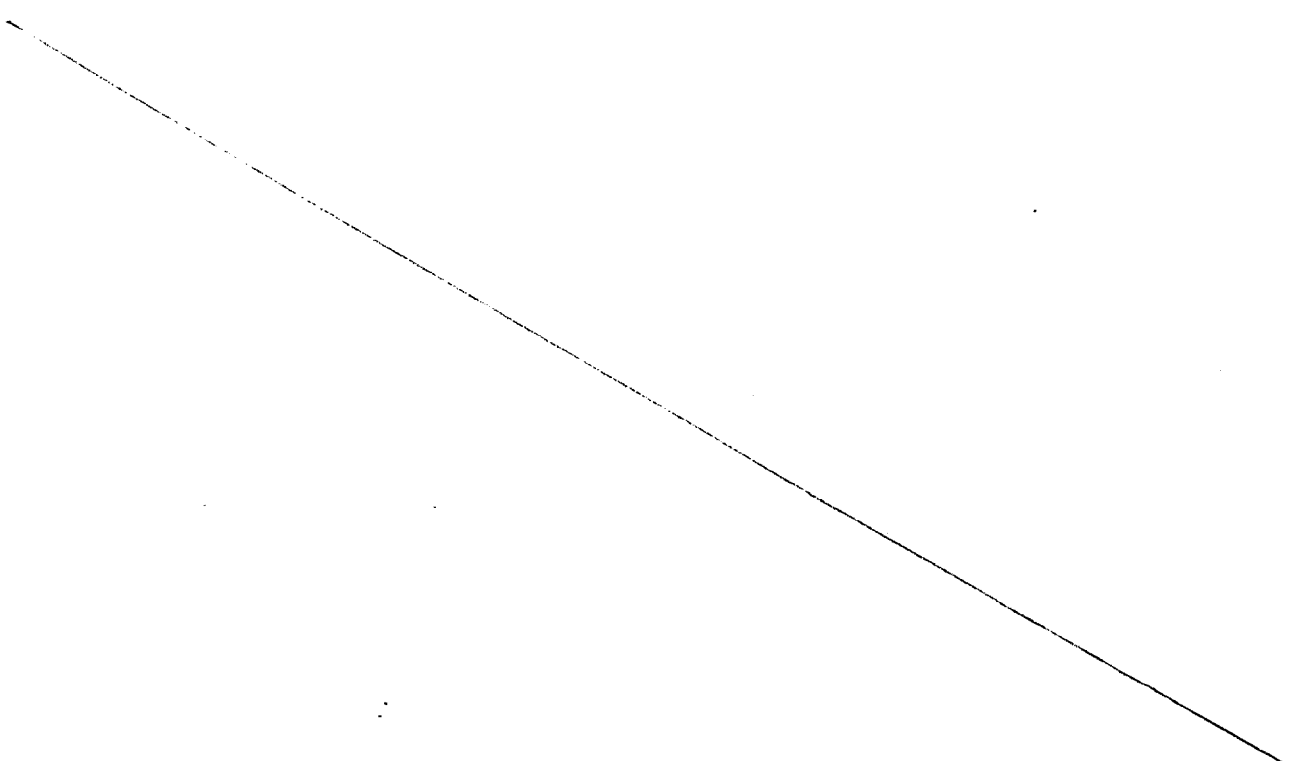
3. Mineral oil (CAS Reg. No. 8012-95-1); or

4. Butylated hydroxytoluene (CAS Reg. No. 128-37-0); as a heat stabilizer for use in rigid poly(vinyl chloride) and rigid vinyl chloride copolymers, complying with §§ 177.1950 and 177.1980, respectively, intended for use in the manufacture of

pipes and pipe fittings that will contact water in food processing plants.

When the petition was first filed on October 21, 1994, it contained an environmental assessment (EA). In that notice of filing, the agency announced that it was placing the EA on display at the Dockets Management Branch for public review and comment. No comments were received. In the FEDERAL REGISTER of July 29, 1997 (62 FR 40570), FDA published revised regulations under part 25 (21 CFR part 25), which became effective on August 28, 1997. On June 4, 1999, the petitioner submitted a claim of categorical exclusion under the new § 25.32(j), in accordance with the procedures in § 25.15(a) and (d). The agency has reviewed the claim of categorical exclusion under § 25.32(j).

The agency has determined under § 25.32(j) that this action is of a type that does not individually or cumulatively have a significant



effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: Aug. 18, 1999  
August 18, 1999

Alan M. Rulis

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Director, Office of Premarket Approval  
Center for Food Safety and Applied Nutrition

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